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Kelly L. McDow-Dunham 43,787
Name of Attorney Registration No.
Signature of Attorney

P&G Case P122

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :

Gregory D. Sunvold

Mark A. Tetrick

Gary M. Davenport

: Confirmation No. 4085

Serial No. 09/609,622

: Group Art Unit 1614

Filed July 5, 2000

: Examiner Susan D. Coe

For NUTRITIONAL COMPOSITIONS FOR WEIGHT MANAGEMENT

BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Enclosed, pursuant to 37 C.F.R. 1.192(a), is Appellant's brief on Appeal for the above application. The Brief is being forwarded in triplicate.

The fee for this Brief on Appeal is \$330 37 CFR 1.17(c).

The Director is hereby authorized to charge the above fee, or any additional fees that may be required, or credit any overpayment to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

By

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Date: March 22, 2004

Customer No. 27752

(BriefonAppealTrans.doc)
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P&G Case P-122

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of :
Gregory D. Sunvold :
Mark A. Tetrick :
Gary M. Davenport :
Gregory A. Reinhart : Filed July 5, 2000
Serial No. 09/609,622 : Group Art Unit 1614
Confirmation No. 4085 : Examiner: Susan D. Coe
For NUTRITIONAL COMPOSITIONS FOR WEIGHT MANAGEMENT

APPELLANT BRIEF PURSUANT TO 37 CFR § 1.192

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P O Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal of Claims 15 – 24 currently pending in the above-captioned patent application. Appellant received a final rejection from the Examiner in an Office Action dated September 29, 2003. A Notice of Appeal, with appropriate extension of time, was submitted by Appellant and was received by the U.S. Patent and Trademark Office on January 23, 2004, causing Appellant's Brief to be due on March 23, 2004. Appellants' Brief is now submitted in triplicate.

REAL PARTY IN INTEREST

The inventors named in the caption of this Brief have assigned the present patent application to The Iams Company.

RELATED APPEALS AND INTERFERENCES

Appellant and Appellant's undersigned attorney are not aware of any appeals or interferences which would be directly affected or have bearing on the Board's decision in this Appeal.

STATUS OF THE CLAIMS

Claims 15 – 24 are currently pending and are the only rejected claims relevant to this Appeal. For reference, these claims are provided herein at the attached Appendix.

STATUS OF THE AMENDMENTS

It is Appellant's understanding that the Examiner has duly entered all amendments submitted during prosecution of the present application. No amendments were submitted subsequent to the Final Office Action dated September 29, 2003.

SUMMARY OF THE INVENTION

Appellant's claimed invention is directed to compositions comprising an effective weight reducing amount of L-carnitine, chromium, Vitamin A, and at least one carbohydrate selected from sorghum, barley, and mixtures thereof, which composition is formulated as a solid pet food. Without limitation, the invention is directed to the needs of consumers to provide their pets with a composition which, when fed to an obese or overweight mammal, assist the pet in losing weight or maintaining weight loss.

In particular, the claimed invention is directed to compositions utilizing the low glycemic grains sorghum, barley, or both. As has been discovered, the inclusion of sorghum and / or barley achieves unexpected effects when combined with the remaining components of the claimed compositions, namely L-carnitine, chromium, and Vitamin A. As described in the originally filed specification, these claimed compositions exhibit superior results relative to alternative compositions. These

superior results are disclosed in Appellant's specification and are measured by surprisingly enhanced weight management benefits in the pet.

ISSUE

There is one issue in the present Appeal:

Whether Claims 15 – 18 and 24, and separately Claims 19 – 23, would have been non-obvious over the combination of Hastings *et al.*, U.S. Patent No. 5,626,849 (herein referred to as "Hastings"), the Purina® CNM Veterinary Product Guide (herein referred to as "Purina"), and Nakatsu *et al.*, U.S. Patent No. 5,240,962 (herein referred to as "Nakatsu").

GROUPING OF CLAIMS

With respect to the issue presented, the grounds of rejection for the issue in view of 35 U.S.C. § 103(a) are collectively applicable to Claims 15 – 18 and 24, and separately collectively applicable to Claims 19 - 23.

Thus, Claims 15 – 18 and 24 stand or fall together, and Claims 19 – 23 stand or fall together.

ARGUMENT

The Examiner has finally rejected Claims 15 – 24 as unpatentable under 35 U.S.C. § 103(a) in view of the combination of Hastings, Purina, and Nakatsu. This rejection of the claims is, respectfully, in error because these claims are non-obvious over the combination of the cited references. Pursuant to 37 CFR § 1.192, Appellant's arguments with respect to this issue is presented for review, as follows:

Summary of Hastings, Purina, and Nakatsu

The Examiner has combined three references to arrive at the rejection at issue:

Hastings *et al.*, U.S. Patent No. 5,626,849 (herein referred to as "Hastings") describes a dietary supplement that can be used as a weight loss composition. The composition contains an essentially dry mixture of 25 mg to 100 mg chromium, 50 mg to 125 mg L-carnitine, 25 mg to 100 mg gamma-linolenic acid, 250 mg to 500 mg (-) hydroxycitric acid, 25 mg to 100 mg choline, 25 mg to 100 mg

inositol, 5 mg to 30 mg antioxidants (*e.g.*, Coenzyme Q10), and 15 to 75 mg herbs (*e.g.*, ginkgo biloba). The dietary supplement is administered twice daily, preferably in two separate portions of 7.325 grams each. The supplement may be provided as an essentially dry mixture and then prepared as a beverage and delivered enterally. The supplement is preferable for human use, although generally mammals are contemplated. Capsules, emulsions, suspensions, cakes, cookies, and weight loss candy bars are described. Hastings fails to describe or even suggest pet foods, or any composition containing vitamin A, sorghum, or barley.

The Purina® CNM Veterinary Product Guide (herein referred to as “Purina”) is a guide which is apparently intended for the benefit of veterinarians as a summary of Purina® dog and cat foods. Purina summarizes at least twelve veterinary diets which are suggested for use in the treatment of a variety of conditions - - ascites, colitis, congestive heart failure, constipation, critical care, diabetes mellitus, diarrhea (small bowel), diarrhea (large bowel), edema, enteritis, exocrine pancreatic insufficiency, fluid retention, gastritis, geriatrics, hepatic disease, hepatic encephalopathy, hyperlipidemia, hypertension, inflammatory bowel disease, lymphangectasia, malabsorption / maldigestion, obesity, pancreatitis, and renal failure. None of the diets are described as containing either of chromium or L-carnitine. Each and every described diet utilizes corn. None of the diets are described as using sorghum. Only one diet, the DCO-Formula prescribed for use in the treatment of diabetes and colitis, uses barley. Of interest, the OM-Formula, prescribed for use in the treatment of obesity management, uses neither sorghum nor barley.

Nakatsu *et al.*, U.S. Patent No. 5,240,962 (herein referred to as “Nakatsu”) describes a composition which employs a naturally occurring alkyl or alkenyl phenol having 15 to 17 carbon atoms in the alkyl or alkenyl group, for use in treating obesity or reduction of fat. These phenols are irrelevant to the requirements of the claimed invention. Nakatsu describes that the phenol may be formulated in a variety of different manners, including as a bolus, powder, solution, paste, syrup, or animal feed, preferably for use by a human. In describing the general art of animal feeds, Nakatsu states that animal feeds can contain grains such as corn, sorghum, wheat, barley, oats and the like, soya meal, or fish meal. The only active described as useful for weight management is the irrelevant phenol, with the grains being described merely as vehicles. Nakatsu fails to describe or suggest the use of chromium, L-carnitine, or Vitamin A.

Prima Facie Case of Obviousness Not Established; No Motivation to Combine

A *prima facie* case of obviousness in view of Claims 15 – 18 and 24 and, separately, Claims 19 – 23, has not been established because the basic criteria of such a case has not been met. To support a rejection in view of a combination of references, obviousness may only be established by combining or modifying the teachings of the prior art where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See MPEP 2143.01. One of ordinary skill in the art would not have been motivated to combine the references which have been cited by the Examiner, and Appellant asserts that the Examiner is using impermissible hindsight to do so.

Hastings merely suggests the use of chromium and L-carnitine, at very specific levels, for use in the described dietary supplements. As this fails to teach or even suggest each and every element of Appellant's claims, including the recitation of Vitamin A and a carbohydrate selected from sorghum and/or barley all formulated as a solid pet food, one of ordinary skill must have been motivated to combine another reference in order for the Examiner to properly construct the argument of obviousness. However, folding in Purina and Nakatsu would not have been motivated for several reasons.

First, the Examiner appears to have overlooked the totality of Purina. The Examiner states that the weight management diet disclosed by Purina uses corn, and uses this as an attempt to obviate the present invention further in view of Nakatsu. However, the Examiner does not recognize in the Office Action that not only the weight management diet but rather *each and every diet described by Purina uses corn* (in the form of ground yellow corn or corn gluten meal, depending on the diet). This includes diets suggested by Purina for the following conditions - - ascites, colitis, congestive heart failure, constipation, critical care, diabetes mellitus, diarrhea (small bowel), diarrhea (large bowel), edema, enteritis, exocrine pancreatic insufficiency, fluid retention, gastritis, geriatrics, hepatic disease, hepatic encephalopathy, hyperlipidemia, hypertension, inflammatory bowel disease, lymphangectasia, malabsorption / maldigestion, obesity, pancreatitis, and renal failure. One of ordinary skill in the art would not have been motivated to select corn specifically for use in a weight management diet in view of Purina.

As such, it is respectfully misleading to argue that Purina is selecting corn for specific use in weight management diets.

Even further, it is not even appropriate to argue that one of ordinary skill in the art would have equated sorghum or barley (as recited in the present claims) with the corn used in every diet of Purina in view of the disclosure of Nakatsu. Read in context, Nakatsu states that the phenols described for use in weight management may be combined in animal feeds. Nakatsu merely states that animal feeds often contain grains such as corn, sorghum, wheat, barley, oats, and the like. The described grains are described merely as vehicles for the feed, not active ingredients for weight management purposes (only the described phenols are attributed as providing this benefit, as described by Nakatsu). There is absolutely no teaching or suggestion that, when utilized as a weight management active, sorghum or barley, or even corn, should be used. Stating that sorghum or barley as described by Nakatsu can be interchanged with the corn of Purina specifically for weight management purposes is a tenuous and inappropriate connection, since Purina describes the use of corn for all described diets and Nakatsu does not delineate any grain for any specific purpose.

Finally, combining each of these references as a piecemeal attempt to construct Appellant's invention in hindsight is improper. The Examiner has merely located a disclosure of each component recited in the present claims, but each disclosure is for a different purpose or formulation and fails to suggest any combination.

As such, Hastings, Purina, and Nakatsu are not properly combined, because there is no motivation to construct such combination. Respectfully, the required *prima facie* case of obviousness has failed.

Three-Prong Test of Obviousness Not Met

Even assuming *arguendo* that a *prima facie* case has been established, the Examiner's rejection still fails with respect to each grouping of claims herein (Claims 15 – 18 and 24, and separately Claims 19 – 23). To support a rejection based on obviousness, the Examiner and the Board are compelled to follow *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), including the three-prong test set forth therein:

1. Determining the scope and contents of the pertinent art;
2. Ascertaining the differences between the pertinent art and the claims in issue; and
3. Resolving the level of ordinary skill with respect to the pertinent art.

While applying Graham, the following tenets must be adhered to: a) the claimed invention must be considered as a whole; b) the pertinent art must be considered as a whole and must suggest the desirability of making the invention; c) the pertinent art must be viewed without the benefit of impermissible hindsight; and d) reasonable expectation of success is the standard with which obviousness is determined. See MPEP § 2141.01 and *Hodosh v. Block Drug Co.*, 229 U.S.P.Q. 182 (Fed. Cir. 1986). The Examiner's rejection based on one above cited combination of references is therefore traversed in view of the foregoing requirements and tenets, as follows:

1. *Determining the Scope and Contents of the Cited Art*

The scope and contents of the cited references are as described herein above.

2. *Ascertaining the Differences Between the Cited Combination of References and the Claims at Issue*

Claims 15 – 18 and 24

With respect to the first grouping of claims, Claims 15 – 18 and 24, key differences between Appellant's claimed invention and the cited combination of references are as follows:

- 1) The present inventors have discovered compositions useful for weight reduction in the pet, comprising L-carnitine, chromium, Vitamin A, and at least one carbohydrate selected from sorghum and barley, wherein the composition is formulated as a solid pet food. Appellant's claimed invention, as set forth in Claims 15 – 18 and 24, is drawn to this discovery.
- 2) Hastings fails to teach or suggest administration of the described supplements to pets such as cats or dogs. Moreover, Hastings fails to teach or suggest any pet food composition at all. Similarly, Nakatsu is directed to compositions which may be formulated in a variety of different manners, including as a bolus, powder, solution, paste, syrup, or animal feed, wherein the preferred user is a human.

- 3) Only one reference, Purina, is directed to pet foods. Each and every diet described by Purina contains corn, which is not a required element of Appellant's claims, and only one diet - - the DCO-Formula prescribed for use in the treatment of diabetes and colitis - - uses barley. The OM-Formula, which is the only prescribed for use in the treatment of obesity management, uses neither sorghum nor barley.
- 4) The Examiner has argued that Nakatsu states that corn may be used interchangeably with sorghum and barley and, since Purina uses corn in its weight management diets, it would have been obvious to substitute sorghum and/or barley for corn into Purina and then use Purina in the supplements of Hastings. Respectfully, the Examiner's argument is flawed for a variety of reasons. Preliminarily, as clarity for the Board, the Examiner repeatedly relies upon a conclusion that Nakatsu states that corn may be used interchangeably with sorghum and barley. However, Nakatsu never states this. Rather, Nakatsu lists a variety of grains and other materials, including "corn, sorghum, wheat, barley, oats, and the like, soya meal, fish meal, etc." that may be optionally used in a solid animal feed. See Nakatsu, Column 5, lines 19 – 41. Moreover, Nakatsu does not describe any purpose for grains or such other materials, other than as convenience for administration. See Nakatsu, Column 5, lines 19 – 24.

Even further, it is not even appropriate to argue that one of ordinary skill in the art would have equated sorghum or barley with corn for weight management purposes in view of the disclosure of Nakatsu. Read in context, Nakatsu states that the phenols described for use in weight management may be combined in animal feeds. Nakatsu merely states that animal feeds often contain grains such as corn, sorghum, wheat, barley, oats, and the like. The described grains are described merely as vehicles for the feed, not active ingredients for weight management purposes (as described by Nakatsu, it is rather the described phenols that provide this benefit). There is absolutely no teaching or suggestion that sorghum or barley, or even corn or any other grain or other material optionally described by Nakatsu, should be used as a weight management active. As such, stating that sorghum or barley as described by Nakatsu can be interchanged with the corn of Purina specifically for weight management purposes is a tenuous and inappropriate connection.

- 5) This connection is even further tenuous and inappropriate because the Examiner appears to have overlooked the totality of Purina. The Examiner states that the weight management diet disclosed by Purina uses corn. However, not only the weight management diet but rather *each and every diet described by Purina uses corn* (in the form of ground yellow corn or corn gluten meal, depending on the diet). This includes diets suggested by Purina for the following conditions - - ascites, colitis, congestive heart failure, constipation, critical care, diabetes mellitus, diarrhea (small bowel), diarrhea (large bowel), edema, enteritis, exocrine pancreatic insufficiency, fluid retention, gastritis, geriatrics, hepatic disease, hepatic encephalopathy, hyperlipidemia, hypertension, inflammatory bowel disease, lymphangectasia, malabsorption / maldigestion, obesity, pancreatitis, and renal failure.
- 6) As such, it is not an appropriate characterization to argue that Purina is selecting corn for specific use in weight management diets, or that Nakatsu suggests that corn, sorghum, and barley can be used interchangeably for Appellant's present purposes.
- 7) Moreover, Appellant's claimed invention requires effective weight reducing amounts of each of the following: L-carnitine, chromium, Vitamin A, and at least one carbohydrate selected from sorghum, barley, and mixtures thereof, wherein these components are formulated as a solid pet food. The cited combination of references fails to teach effective weight reducing amounts of Vitamin A, since there are no descriptions of Vitamin A for purposes of effecting weight management (Purina may utilize Vitamin A in its weight management diet, but just like its use of corn, the Vitamin A is used for *all* described diets). Moreover, none of the references discloses or even remotely suggests that Vitamin A is at all useful for weight management purposes.

Claims 19 – 23

With respect to the second grouping of claims, Claims 19 – 23, the arguments presented above with respect to Claims 15 – 18 and 24 are similarly applicable. In addition, further key differences between Appellant's claimed invention and the cited combination of references are as follows:

- 1) The present inventors have discovered compositions useful for weight reduction in the pet, comprising from about 15 to 195 ppm L-carnitine, from about 10 to about 500 micrograms chromium, from about 50,000 IU to about 1,000,000 IU Vitamin A, all per

kilogram of the composition, and at least one carbohydrate selected from sorghum and barley, wherein the composition is formulated as a solid pet food. Appellant's claimed invention, as set forth in Claims 19 – 23, is drawn to this discovery.

- 2) In addition to the arguments set forth above with respect to Claims 15 – 18 and 24, the cited combination of references further fails to teach or suggest the refined elements of Claims 19 – 23. These claims recite compositions comprising from about 15 to 195 ppm L-carnitine, from about 10 to 500 micrograms of chromium, and from about 50,000 IU to about 1,000,000 IU of Vitamin A *per kilogram* of the composition. As summarized in the following table, these are exceedingly lower doses of L-carnitine and chromium relative to those described in Hastings - - Hastings describes use of 50 to 125 mg of L-carnitine and 25 to 100 micrograms of chromium *per 7.325 grams of the described dietary supplement*. Levels of Vitamin A are not described by any of the references:

	L-Carnitine (per kilo)	Chromium (per kilo)	Vitamin A (per kilo)
Claimed Invention	From about 15 to 195 milligrams	From about 10 to 500 micrograms	From about 50,000 IU to about 1,000,000 IU
Hastings	Approximately: 6,800 to 17,000 milligrams	Approximately: 3,400 to 13,600 micrograms	Not described at all
Purina	Not described at all	Not described at all	Apparently used as nutrient only; no levels described
Nakatsu	Not described at all	Not described at all	Not described at all

As is evident from the table, the claimed invention requires specific, low levels of each of L-carnitine, chromium, and Vitamin A. In contrast, Hastings discloses at least *80-fold* higher L-carnitine levels relative to that recited in the claimed invention, and at least *27-fold* higher chromium levels relative to that recited in the claimed invention. Even further, there is no guidance from the cited reference, either alone or in combination, as to what levels of Vitamin A to select (or, further, to even use Vitamin A as a weight management component at all). As such, even in combination, the references fail to arrive at, or even suggest, the claimed invention.

- 3) Appellant moreover reiterates the arguments set forth above with respect to Claims 15 – 18 and 24, in particular with reference to the selection of barley or sorghum as a required

grain source of the present invention as contrasted against the deficiency of disclosure or suggestion with respect to such grains in the cited combination of references.

3. Resolving the Level of Ordinary Skill with Respect to the Cited Combination of References

In view of the cited references, the ordinarily skilled artisan would have failed to recognize Appellant's claimed invention. Specifically, the ordinarily skilled artisan having the benefit of disclosure relating to piecemeal use of L-carnitine, chromium, Vitamin A, and various grain sources, for a variety of purposes other than weight management and not in any context of a solid pet food, would have failed to recognize the claimed invention as set forth in Claims 15 – 18 and 24 and, separately, Claims 19 – 23.

4. Argument Based on Graham Inquiries and the Relevant Tenets

As has been set forth above, a *prima facie* case of obviousness has not been properly constructed by the Examiner, because one of ordinary skill in the art would not have been motivated to combine Hastings, Purina, and Nakatsu for any purpose, including for the purpose of providing a solid pet food having weight management benefits.

Even assuming *arguendo* that a *prima facie* case had been established, in addition to the differences between the cited combination and the present invention (as will be summarized below), Appellant has overcome the presumption of obviousness by a showing of unexpected results. Page 9 of the specification reports the results of a comparative feeding study. At page 9, it is reported that "Diet B," which comprises a combination of sorghum and barley as a low glycemic index carbohydrate source, produced optimized weight loss relative to "Diet A" (which did not contain chromium, sorghum, or barley). As further information, Appellants refer the Board to page 7 of the specification which states that Diet A was Hill's® Prescription Diet® w/d® Canine and that Diet B was Eukanuba Veterinary Diets® Nutritional Weight Maintenance Formula™ Glucose-Control™/Canine supplemented with the described amounts of chromium and sorghum and barley. Results indicated that dogs which were fed Diet B lost more body fat than dogs which were fed Diet A. Moreover, dogs which were fed Diet B also tended to accumulate lean body mass while dogs which were fed Diet A merely maintained lean body mass.

Accordingly, Appellants assert that the invention as claimed herein would not have been obvious in view of the cited combination of references. To sum, the use of sorghum and / or barley achieves

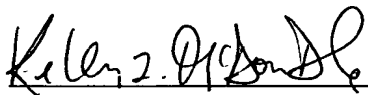
unexpected effects when combined with the remaining components of the claimed compositions. The use of sorghum or barley for this purpose is neither taught nor suggested in the cited combination of references. As stated, the Examiner has appears to have constructed the rejection by substituting corn with sorghum or barley based on the following tenuous and improper connections: 1) Nakatsu states that animal feeds can contain corn, sorghum, wheat, barley, oats and the like (but the Examiner fails to recognize that the use of such grains is as a vehicle only, not as a weight management active); and 2) Purina uses corn in its weight management diet (but corn is used in *all* of the described diets, not just the weight management diet). Moreover, Appellant has provided evidence of unexpected results as set forth in the specification as filed. In view of the foregoing, and these unexpected results, Appellant respectfully requests that the Board direct the Examiner to promptly withdrawal of the present rejection based on obviousness.

SUMMARY OF ARGUMENT AND RELIEF REQUESTED

Appellant asserts that the compositions recited in Claims 15 – 18 and 24 and, separately, Claims 19 – 23, are indeed non-obvious over the cited references under 35 U.S.C. § 103(a).

Accordingly, Appellant respectfully requests the Honorable Board of Appeals and Interferences to reverse the Examiner's rejection and remand with directions to allow the present application to issue with Claims 15 – 24 as currently pending.

Respectfully Submitted for Appellant,

By: 

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Customer No. 27,752
March 22, 2004

APPENDIX

Pending Claims for U.S. Patent Application Serial No. 09/609,622

1 – 14. (*Previously Canceled*).

15. (*Previously Amended*) A composition comprising an effective weight reducing amount of L-carnitine, chromium, Vitamin A, and at least one carbohydrate selected from the group consisting of sorghum, barley, and mixtures thereof, which composition is formulated as a solid pet food.

16. (*Previously Presented*) The composition of claim 15 which comprises sorghum.

17. (*Previously Presented*) The composition of claim 15 which comprises barley.

18. (*Previously Presented*) The composition of claim 15 which comprises sorghum and barley.

19. (*Previously Presented*) The composition of claim 15 which comprises from about 15 to 195 ppm L-carnitine, from about 10 to about 500 micrograms of chromium, and from about 50,000 IU to about 1,000,000 IU of Vitamin A per kilogram.

20. (*Previously Presented*) The composition of claim 15 which comprises from about 20 to 150 ppm L-carnitine per kilogram.

21. (*Previously Presented*) The composition of claim 15 which comprises from about 50 to 100 ppm L-carnitine per kilogram.

22. (*Previously Presented*) The composition of claim 15 which comprises from about 50,000 IU to about 500,000 IU of Vitamin A per kilogram.

23. (*Previously Presented*) The composition of claim 15 which comprises from about 50,000 IU to about 150,000 IU of Vitamin A per kilogram.

24. *(Previously Presented)* The composition of claim 15 further comprising from about 18 to about 40 weight percent crude protein, from about 4 to about 30 weight percent fat, and from about 2 to about 20 weight percent total dietary fiber.